US Army Medical Research and Development Command
Regulatory Review Requirements
Regulatory Review Submission Template for Funded Projects

This Form Should Be Completed By the Funding Agency

Purpose: The Office of Research Protections Human Research Protection Office (ORP HRPO) and Animal Care and Use Review Office (ORP ACURO) now use the U.S. Army Medical Research and Development Command's Electronic Grants System (EGS) as its review platform for all research that requires ORP HRPO or ACURO approval. Please complete all applicable sections of the attached ORP Proposal Submission Form to enable creation of a record in the EGS. An individual who oversees/is familiar with the funding of the research should complete the form, e.g., the COR, Program Manager, Science Officer.

Instructions: Please complete the template and submit with proposal documents to ORP electronic mailboxes. Animal research should be submitted to the ACURO mailbox usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil, human or cadaver research submitted to the HRPO mailbox usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil, and both types of research to both ACURO and HRPO boxes.

View Form Instructions | Validate | Reset | Save Form

SECTION I: PROGRAM AND AWARD INFORMATION

System Log Number: *(if applicable)*

(Examples: DTRA ROB Number (e.g., CB-2019-##); OTA Base Agreement Number (e.g., 2018-833); MCS Proposal Log Number; etc…)

Award Number:

(Examples: MRDC Contract Number; MIPR/FAD # (e.g., HDTRA 1828370 funded through W15QKN-16-9-1002, OTA Agreement #)

Program Management Office:

Other PMO:

Fiscal Year: 2021

Program Management Office Contact:

(Examples: COR/STM/PM/SO)

PMO Prefix | **PMO First Name** | **PMO Last Name**

PMO Email Address | **PMO Telephone**

Award Administration Contact:

(Examples: Contract/Grant Specialist)

Award Admin Prefix | **Award Admin First Name** | **Award Admin Last Name**

Award Admin Email Address | **Award Admin Telephone**

SECTION II: PROPOSAL INFORMATION

Proposal Title:

Period of Performance (*if known*)**:** to

POP Start Date | POP End Date

Proposal Investigator Information:

Proposal Investigator Prefix | Proposal Investigator First Name | Proposal Investigator Last Name

Proposal Investigator Email Address | Proposal Investigator Telephone

Proposal Investigator Degree(s) *if known* **or Suffix**

Proposal Investigator institution:

PI street address line 1:

PI street address line 2:

Proposal Investigator city:

Proposal Investigator state:

Proposal Investigator zip code:

Proposal Investigator country: UNITED STATES

Is this project linked to a prior or on-going DOD/USAMRDC Award(s), if known?

- ◯ No
- ◯ Yes (If yes, please describe below)

HRPO/ACURO Log Number *(if known)*	System Proposal/ Log Number *(if known)*	Award Number	Active (Y/N)	Funding Activity/Program Office

Estimated ACURO Start *(if known)*: *(Example: Animal research will start right away)*

Estimated HRPO Start *(if known)*: *(Example: Human Subject research projected in year 2)*

SECTION III: DoD/USAMRDC Proposal Documentation for Submission

(please check all documents submitted)

Documents **required at the time of submission:**

- ☐ Proposal
- ☐ Statement of Work (SOW)

Documentation of scientific merit ***when available*:**

- ☐ Award/funding documentation
- ☐ Statement of scientific merit

SECTION IV: ORP CHECKLIST

Please indicate Yes or No, and provide additional notes to ORP
(Indicate Animal &/or Human Use, as applicable)

ACURO	Yes	No	Notes to ACURO
Animals used?	☐	☐	
ACURO appendix provided?	☐	☐	
IACUC approval?	☐	☐	
Animal protocol provided?	☐	☐	

Human Cell Line Use	Yes	No	Notes to HRPO (cell line use)
Research involves cell lines?	☐	☐	
Commercially available (for purchase) cell lines used?	☐	☐	
Non commercially available (not for purchase) cell lines used?	☐	☐	
Commercially available human embryonic cell lines used?	☐	☐	
Cell lines of unknown source used?	☐	☐	
Optional verification documentation (e.g. Claim of Exemption or letter)?	☐	☐	

Human Anatomical Substances and Human Data Use	Yes	No	Notes to HRPO (anatom. substance and human data use)
Human anatomical substances or data used?	☐	☐	
HRPO submission form on use of data/specimen form provided?	☐	☐	
IRB letter or institutional letter provided?	☐	☐	

Human Subjects	Yes	No	Notes to HRPO (human subject use)
1) Human subjects used?	☐	☐	
a) Human use exempt study?	☐	☐	
b) Local IRB approval provided?	☐	☐	
c) Detailed human subject protocol provided?	☐	☐	
d) Informed consent documents provided?	☐	☐	
2) Proposal includes clinical trial(s)?	☐	☐	
a) FDA regulated?	☐	☐	
b) Planned emergency research with trauma patients?	☐	☐	

Cadaver Use	Yes	No	Notes to HRPO (cadaver use)
Cadaver use?	☐	☐	
ORP cadaver checklist provided?	☐	☐	

SECTION V: SAFETY AND ENVIRONMENT (*for MRDC Extramural research ONLY*)

Please indicate Yes or No, and provide additional notes where applicable

Environment	Yes	No	Notes to Safety and Environment
Involves army provided infectious agents?	○	○	
Involves use of biological select agents or toxins (BSAT)?	○	○	
Involves use of specific chemical agents?	○	○	
Involves pesticides outside of established lab?	○	○	
Potential likelihood of significant negative effects on public health, safety or environment?	○	○	

Biological select agents and toxins (BSAT) Chemical Agents List *(See page 7)*

SECTION VI: INFORMATION OF THE PERSON WHO COMPLETED THE FORM

First Name:

Last Name:

Email Address:

Phone Number:

Office:

Title:

Validate Reset Save Form

Return to Safety/Environment

Chemical Agents

Schedule 1 Chemical Agents
Sarin
Soman
Tabun
VX
Ricin
Sulfur mustards
Lewisites
Nitrogen mustards
Saxitoxin

Schedule 2 Chemical Agents
Amiton
PFIB
3-Quinuclidinyl benzilate

Schedule 3 Chemical Agents
Phosgene
Cyanogen chloride
Hydrogen cyanide
Chloropicrin